K031572 1 page 1 of 2

ZMR® Hip System-XL
Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Karen Cain Manager, Regulatory Affairs Telephone: (574) 372-4219 Fax: (574) 372-4605
Date:	May 16, 2003
Trade Name:	*ZMR*® Hip System-XL
Common Name:	Total hip prosthesis
Classification Name and Reference:	Hip joint metal/polymer semiconstained uncemented prosthesis, no 21 CFR reference Hip joint metal/polymer/metal semiconstrained porous coated uncemented prosthesis, 21 CFR 888.3358
Predicate Devices:	*ZMR*® Hip System-Revision Taper, manufactured by Zimmer, Inc., K992667, cleared October 27, 1999 *ZMR*® Hip System-Porous Revision, manufactured by Zimmer, Inc., K994286, cleared March 10, 2000
Device Description:	Like its predicates, the *ZMR*® Hip System–XL prosthesis is a modular femoral stem manufactured from *Tivanium*® Ti-6Al-4V Alloy and intended for cementless use in revision hip arthroplasty. This device has two modular junctions: a head/neck junction and a midstem junction. Three components are intraoperatively assembled to construct the device: a proximal "body," a distal stem, and a compression nut.

Intended Use:	The *ZMR*® Hip Prosthesis is intended for revision hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur.
Comparison to Predicate Device:	The modifications to the *ZMR*® Hip System change neither the intended use nor the fundamental scientific technology of the device. The *ZMR* XL components are manufactured, packaged and sterilized using the same processes and materials.
Performance Data:	Non-clinical performance testing demonstrated that the device is equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2003

Ms. Karen Cain
Manager, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Re: K031572
Trade/Device Name: ZMR® Hip System-XL
Regulation Number: 21 CFR 888.3358 and 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis and Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: LPH and LWJ
Dated: May 16, 2003
Received: June 3, 2003

Dear Ms. Cain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

JUN 2 4 2003

Indications for Use

510(k) Number (if known): K031572

Device Name:

ZMR® Hip System-XL

Indications for Use:

The *ZMR* Hip Prosthesis is indicated for total hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur. Arthroplasty should be performed only when more conservative methods of treatment have failed to provide symptomatic relief or when there is progressive disability.

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes (Per 21 CFR 801.109) OR Over-The-Counter Use No (Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031572